Attorney Docket No. 01/090 LTS
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Neuland *et al.*

Application No. 10/501,247

Filed: July 12, 2004

For: METHOD FOR NEUTRALIZING
OR RECYCLING CARRIER MATERIALS
FOR FILM-LIKE COATINGS

Group Art Unit: 1615

Examiner: C. E. Helm

Confirmation No.: 5234

APPEAL BRIEF

MS Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Charlotte, North Carolina
November 14, 2011

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant submits this Appeal Brief to the Board of Patent Appeals and Interferences in response to the non-final Office Action of June 16, 2011. A Notice of Appeal was timely filed in the above-referenced application on September 15, 2011.

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I. REAL PARTY IN INTEREST

The real party in interest is LTS Lohmann Therapie-Systeme AG who owns the entire right, title and interest in and to the subject application. Assignment to LTS Lohmann Therapie-Systeme AG was recorded in the United States Patent and Trademark Office on July 12, 2004, at Reel/Frame 015733/0527.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and Assignees are unaware of any prior or pending appeals, interferences or judicial proceedings related to, directly affected by or having a bearing on the subject appeal.

III. STATUS OF THE CLAIMS

Claims 1, 3 and 5 through 10, which are all under appeal, stand rejected and are found in the Claims Appendix. Claims 2 and 4 have been canceled. No claim is allowed.

IV. STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendment has been filed in response to the rejection issued in the non-final Office Action of June 16, 2011.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to methods of forming drugs, foods and cosmetics (hereinafter referred to as "consumables") in film-form. In general, film-form consumables are manufactured on fully automated production lines by forming thin sheets of an active-ingredient film on a carrier material. Such processes may be either continuous or as discrete batches. Batch operations are attractive, as the materials used to form the active-ingredient film may be readily changed. In forming consumable films via a batch operation, the active-ingredient containing film is usually peeled off of the carrier material and the separated carrier material is taken up onto a reel.

Unfortunately, the active-ingredient (as well as any additional adjuvants or other coating compounds) can penetrate into the carrier material due to diffusion. The carrier material is then contaminated by these substances, up to their respective degree of saturation. Consequently, once the active ingredient containing film has been peeled off the carrier material, the contaminated carrier material cannot be used again within a subsequent batch, since it is loaded to a non-specified degree with diffused active ingredients and the like (hereinafter referred to as "contaminants," as noted above). The required disposal such contaminated carrier material presents both an economic and environmental challenge.

Surprisingly, Applicants have found that drug, food and cosmetic contaminants can be evaporated from carrier materials using simple thermal treatments performed at moderate temperatures and dwell times, such as at a temperature of approximately 80 °C for approximately 0.5 to 6 minutes, and the evaporated contaminants can then be permanently disposed of by feeding the evaporated contaminants to a thermal after-burner using controlled air circulation.

Altogether unexpectedly, the foregoing decontamination does not significantly detrimentally impact the physical properties of the carrier material. Hence the decontaminated carrier material, also referred to as neutralized carrier material, may then be reused as a carrier within the active-ingredient film forming process.

The subject matter of independent Claim 1 is thus directed to methods for removing contaminating substances from a carrier material that includes heating an active-ingredient-containing drug, food or cosmetic-containing coating to approximately 40 to 100 °C, coating the heated active-ingredient- containing coating onto a neutralized carrier material that was supplied on a reel via synchronized rollers during which substances within the coating diffuse into and contaminate the carrier material with drug, food or cosmetic contaminating substances. The coated carrier material is then dried to form an active-ingredient-containing drug, food or cosmetic film, and the dried active-ingredient- containing film is peeled off the contaminated carrier material. The contaminated carrier material is then subjected to a thermal treatment that includes passing the contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminating substances from the carrier material, thereby forming neutralized carrier material. The contaminating substances that were removed are fed to thermal after-burning using controlled air circulation. The neutralized carrier material is returned to be coated again. The thermal treatment is performed at a temperature of approximately 80 °C and the period of time sufficient to remove essentially all of the undesired substances from the carrier material is approximately 0.5 to 6 minutes. The carrier material is paper, a polymer or a composite material composed of paper, polymer or a thin metal foil or polymer and a thin metal foil. See Specification, Page 1, lines 13 through 25; Page 1, lines 29 through 30; Page 2, lines 28 through 32; Page 3, lines 1 through 5; Page 4, lines 10 through 31; Page 5, lines 4 through 10 and Page 5, lines 12 through 14.

Claim 5 is directed to methods for removing contaminating substances from a carrier material that includes heating an active-ingredient- containing drug, food or cosmetic aqueous coating to approximately 40 to 100 °C, coating the heated aqueous active-ingredient- containing coating onto carrier material via synchronized rollers, during which substances within the aqueous coating composition diffuse into and contaminate the carrier material. The coated carrier material is then dried to form an active-ingredient-containing drug, food or cosmetic film, and the dried film is peeled off the contaminated carrier material. The contaminated carrier material is subsequently subjected to a thermal treatment that includes passing the contaminated

carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminating substances from the carrier material, and the removed contaminating substances are subjected to a thermal after-burning using controlled air circulation. See Specification, Page 1, lines 13 through 25; Page 1, lines 29 through 30; Page 2, lines 28 through 32; Page 3, lines 1 through 5; Page 4, lines 10 through 31; Page 5, lines 4 through 10; Page 5, lines 12 through 14 and Page 4, lines 27 through 28.

Claim 6 is directed to methods for removing contaminating substances from a carrier material that includes heating an active-ingredient- containing drug, food or cosmetic-containing coating to approximately 40 to 100 °C, coating the heated active-ingredient-containing coating onto carrier material via synchronized rollers, during which active ingredients, adjuvants, flavors, or fragrances within the coating diffuse into and contaminate the carrier material. The coated carrier material is then dried to form a drug-containing film, confectionary-containing film, food -containing film or cosmetics-containing film, and the dried film is peeled off the contaminated carrier material. The contaminated carrier material is subsequently subjecting to a thermal treatment that includes passing the contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the contaminating substances from the carrier material, and the removed contaminating substances are subjected to a thermal after-burning using controlled air circulation. See Specification, Page 1, lines 13 through 25; Page 1, lines 29 through 30; Page 2, lines 28 through 32; Page 3, lines 1 through 5; Page 4, lines 10 through 31; Page 5, lines 4 through 10; Page 5, lines 12 through 14; Page 4, lines 11 through 13 and Page 3, lines 5 through 7.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 3, 5, 6, 9 and 10 stand rejected over United States Patent No. 4,569,837 (Suzuki) in view of United States Patent No. 4,925,670 (Schmidt); United States Patent Application Publication No. 2001/0006677 (McGinity); United States Patent No. 2,486,258 (Chavannes)(including applied but not-cited United States Patent No. 2,575,046, also to Chavannes (Chavannes-2) and applied but not-cited United States Patent No. 6,183,775 (Ventouras)); United States Patent No. 4,079,106 (Goldsworthy) and United States Patent No. 4,622,761 (Barth).

B. Claims 1 and 7 stand rejected over Suzuki in view of Schmidt; McGinity; Chavannes; Goldsworthy; Barth and further in view of Lerdkanchanaporn et al., Thermochimica Acta 2000 357-358:71-78, (Lerdkanchanaporn A) and Lerdkanchanaporn et al., Journal of Thermal Analysis 1887 49:879-886 (Lerdkanchanaporn B).

C. Claims 1 and 8 stand rejected over Suzuki in view of Schmidt; McGinity; Chavannes and Goldsworthy and further in view of United States Patent No. 4,978,836 (Dieudonne) and United States Patent No. 5,112,220 (Wimberger).

VII. ARGUMENT

A. Claims 3, 5, 6, 9 and 10 are patentable over Suzuki in view of Schmidt; McGinity; Chavannes; Chavannes-2, Ventouras, Goldsworthy and Barth.

A1. Claims 3, 5, 6, 9 and 10 are patentable over Suzuki in view of Schmidt; McGinity; Chavannes; Goldsworthy and Barth because, inter alia, their combination was improper.

The combination of Suzuki, Schmidt, McGinity, Chavannes; Goldsworthy and Barth is improper because Chavannes (including applied but not-cited Chavannes-2 and Ventouras), Goldsworthy and Barth are in a different field of endeavour from the remainder of the references and the claimed invention, and none of references are pertinent to the particular problem with which the inventor is involved.

A reference qualifies as prior art for an obviousness determination under § 103 only when it is analogous to the claimed invention. In re Klein, No. 2010-1411, slip op at 7 (Fed. Cir. June 6, 2011)(citing *Innovention Toys, LLC v. MGA Enteratinment, Inc.* No. 2010-1290, slip op. at 12 (Fed. Cir. Mar. 21, 2011); *In re Bigio*, 38 F.3d 1390, 1325 (Fed. Cir. 2004); *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992). Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with the inventor is involved. *Id.* A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. *Id* citing *Clay*, 966 F.2d at 659 ("If [a reference] is directed to a different purpose, the inventor would accordingly have had less motivation to consider it.")

The present invention is directed to methods by which to remove active-ingredient-contaminants that have diffused into carrier materials used to produce consumable active-ingredient-containing films, so that the carrier materials may be used to form further consumable

films. Chavannes is directed to methods to form decorative films having an embedded design. Applied but not-cited Chavannes-2 is directed to undulating and/or scintillating decorative films. Applied but not-cited Ventouras is directed to lozenges. Goldsworthy is directed to methods by which to make reinforced foam blocks. Barth is directed to dryers having cup-shaped sections used to dry coatings on transdermal therapeutic systems. Consequently, Chavannes, Goldsworthy and Barth are clearly not within the inventor's field of endeavour.

Chavannes, Goldsworthy and Barth are further not directed to methods by which to remove contaminants that have diffused into a carrier material, but are instead directed to significantly different purposes, i.e. they solve altogether different problems. Chavannes is directed to decorative films that provide proper registration and have improved durability. (US 258, Col. 1, lines 15 - 22). Goldsworthy is directed to continuous processes by which to form X-Y-Z reinforced foam insulation. (US 106, Col. 1, lines 50 – 60). Barth is directed a particular apparatus for drying impregnated transdermal therapeutic systems that eliminates dead spaces and the like within the dryer interior, thereby preventing inter-batch contamination from medicine deposited on the dryer walls. (US 761, Col. 1, lines 20 – 65).

None of these secondary references is reasonably pertinent to the particular problem with which the inventor is involved, i.e. the removal of diffused contaminants from a carrier material used to form consumable films. Specifically, none of these secondary references logically would have commended themselves to the inventor's attention in considering the problem of contaminants diffused within a carrier material, much less a carrier material used to form consumable films. Chavannes, Chavannes-2, Ventouras, Goldsworthy and Barth are neither directed to the removal of contaminants that have diffused into carrier material or even to consumable films. Specifically, Chavannes, whose purpose is to improve the registration and durability of decorative films; Chavannes-2, whose purpose is to provide an undulating and/or scintillating decorative films; Ventouras, whose purpose is provide extended release lozenges; Goldsworthy, whose purpose is to make reinforced foam insulation in a continuous process, and Barth, whose purpose is to provide a dryer with minimal dead space, simply do not have the same purpose and do not relate to the same problem as the claimed invention.

Accordingly, the combination of Chavannes, Chavannes-2, Ventouras, Goldsworthy and Barth with the remaining references is improper, and they should be entirely excluded from consideration in the non-obviousness analysis. None of the remaining references, directed to consumable films, teaches or suggests the removal of contaminants from carrier material.

A2. Claims 3, 5, 6, 9 and 10 are patentable over Suzuki in view of Schmidt; McGinity; Chavannes (including Chavannes-2 and Ventouras); Goldsworthy and Barth because, inter alia, the claimed invention solved an unrecognized problem.

The claimed invention is patentable because none of the cited references recognizes contaminants which have diffused into a carrier material as an issue, and most certainly not contaminants that have diffused into a carrier material used to form consumable films.

An obviousness rejection under 35 U.S.C. § 103 is appropriate only when the differences between the claimed invention and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *In re Dembiczak*, 175 F.3d 994, 50 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1999); 35 U.S.C. § 103 (a). The ultimate determination of whether an invention would have been obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) any objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 – 18, 148 USPQ 459, 467 (1966).

Previously unknown problems can constitute patentable differences between the claimed invention and the prior art. A patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified, for example. *In re Zurko*, 42 USPQ2d 1476, 1479 (Fed. Cir. 1997); see also *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008)(holding that "[e]ven where a general method that could have been applied to make the claimed product was known and within the level of

skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.")

In the instant case, the plethora of cited references simply does not recognize the contamination of carrier materials by active-ingredient-contaminants that have diffused down into the carrier materials as problematic, in contrast to the urgings within the outstanding Office Action on Page 19. Only two of the cited references note the cleaning of foraminious surfaces, and these teachings are merely brief, generic references within larger, altogether unrelated disclosures. Chavannes initially notes that its carrier has been coated so that" it will not be attacked" by components within the coating, and goes on to note the optional provision of "a driven buffing brush ... the purpose of which is to clean the carrier". (US 258, Col. 3, lines 29 – 37 and Col. 6, lines 56 – 61). Applied but not-cited Chavannes-2 merely teaches that polyvinyl alcohol may be used as a permanent coating on a carrier surface to provide a "smooth outer surface" for a subsequently applied vinyl-acetate organosol or dispersion. (Col. 4, lines 1 – 20). Applied but not-cited Ventouras merely teaches that polyvinyl alcohol may be included as a swellable polymer in lozenges. (Col. 2, lines 48 – 59). Goldsworthy generically states that its "tenter frames, chains and belts are then cleaned, mechanically or with heat or solvents, re-coated with a wax or an equivalent release agent, and automatically returned to the initial portion of the machine." (US 106, Col. 2, lines 43 – 47). Chavannes (including Chavannes-2) and Goldsworthy do not teach or suggest that contaminants diffuse into their foraminious surfaces. In fact, Chavannes and Goldsworthy both apply coatings onto the surface of their respective carrier or belts that would instead be expected to repel contaminant diffusion.

The Examiner notes in the outstanding Office Action at Page 19, first partial paragraph that "[d]iffusion is a well-known thermodynamic phenomenon." While this is undoubtedly true, none of the plethora of references, including three references directed specifically to consumable films, notes the diffusion of contaminants into a carrier material as problematic. Thus those skilled in the art at the time the invention was made simply did not recognize the diffusion of the contaminants from the active-ingredient-containing-film into the carrier as an issue.

Consequently, it is irrelevant whether it was known that drugs would diffuse from polyvinyl alcohol, as urged within the outstanding Office Action on Page 19, first partial paragraph.

Nor would there have been any reason for Chavannes (including Chavannes-2) or Goldsworthy to have been concerned about contaminants diffusing into their foraminious surfaces, as it would not be expected that such contamination would affect the performance of their decorative films or foam insulation. Chavannes and Goldsworthy's teachings are instead directed to the surface cleaning of their foraminious surfaces, for example via Chavannes' buffing brush. The only other reference to "contamination" is within Barth, who is concerned with contamination on the interior of a dryer used to produce transdermal therapeutic systems. The remainder of the references merely disclose that consumable films and methods to form them are known. In fact, newly cited Schmidt teaches that the carrier material remains with the consumable film until its consumption. Hence none of the cited references recognizes contaminants which have diffused from a film down into a carrier material as an issue, and most certainly not contaminants that have diffused into a carrier material used to form consumable films. Instead it is "Applicants [who] teach that components of the coating will penetrate into carrier material," as indicated in the outstanding Office Action on Page 7, last sentence in its entirety. Accordingly, Applicants respectfully submit that the claimed invention is patentable in light of the cited references (including the applied but not-cited references).

A3. Claims 3, 5, 6, 9 and 10 are patentable over Suzuki in view of Schmidt; McGinity; Chavannes; Goldsworthy and Barth because, inter alia, the claimed invention provides more than predictable results.

The claimed invention is patentable because none of the cited references teaches or suggests that thermal treatment could remove contaminants which have diffused into a carrier material, thus the claimed invention provides more than predictable results.

The USPTO has issued guidelines to its Examiner's pointing out that the *KSR* decision (*KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734, 82 USPQ2d 1385, 1392 (2007)) reaffirmed the analytical framework for obviousness that was presented in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). *Fed. Register*, Vol. 75, No. 169, Sept. 1, 2010, p 53643 – 53647. The guidelines note that Examiners must provide a reasoned explanation as to why the invention as claimed would have been obvious to a person of ordinary skill in the art at the time of the invention. *Id* at p 53645.

The clear articulation of the reason(s) why the claimed invention would have been obvious is key to supporting any rejection under 35 USC § 103. Under KSR, the analysis supporting an obviousness rejection should be made explicit. KSR said such rejections "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," quoting *In re Kahn*, 441 F.3d 977, 78 USPQ2d 1329 (Fed. Cir. 2006).

The guidelines further encourage Examiners to "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id* at p 53646 (citing KSR, 550 U.S. at 401). The guidelines caution that "merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness. In accordance with MPEP § 2143 A(3), a proper rejection based on the rationale that the claimed invention is a combination of prior art elements also includes a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art." Fed. Register at 53647 citing *Crocs, Inc. v. U.S. International Trade Commission*, 598 F.3d 1294 (Fed. Cir. 2010).

None of the cited references, discussed in greater detail below, teaches or suggests that thermal treatment could remove contaminants which have diffused into a carrier material. The cited references instead indicate that mechanical and thermal treatments would provide equivalent results, which suggests that thermal treatments would be expected to provide only surface cleaning.

Suzuki is directed to pharmaceutical preparations for periodontal disease. (US 837, Col. 2, lines 16 – 18). Suzuki notes that its medicinal agent is dissolved in polymer, cast and dried. (US 837, Col. 5, lines 40 – 45). Suzuki generically notes that its compositions may be cast onto a glass plate, metal plate, drum or "endless belt." (US 837, Col. 6, lines 3 – 8). The working examples of Suzuki cast the medicinal compositions onto a glass plate or subject them to compression molding. (US 837, Col. 6, line 53 through Col. 10, line 55).

Schmidt is directed to film-like carrier material having an active agent-containing coating on one side thereof, in which the active agent-containing coating is removed from the carrier material after it is subdivided into dosage units. (Col. 2, lines 22 – 29). As the individual dosage units are removed from the carrier, the carrier remains in existence until the drug has been used up. (Col. 4, lines 20 – 25).

McGinity is merely directed to extruded effervescent films having a controlled rate of disintegration. (US 677, Para. 0001). The impetus of McGinity is that extrusion allows for extremely short exposure times to elevated temperatures than batchwise hot-melt methods, and further does not require solvents. (US 677, Para. 0025). The films of McGinity are formed by extruding the effervescent mixture and either rolling the resulting film extrudant directly into a tape or cutting it into pieces. (US 677, Para. 0095).

Chavannes is directed to films having an embedded design. (US 258, Col. 1, lines 23 – 30). An "engraved roller" applies an initial "film-forming substance," which may contain solvent such as methyl ethyl ketone, to a carrier. (US 258, Col. 3, line 48 – Col. 4, line 2). The carrier bearing the design imparted by the engraved roll is then passed through a coating apparatus that applies a further layer of film-forming substance over the design. (US 258, Col. 4, lines 58 – 60). The films of Chavannes are formed on a "continuous carrier" that has been coated so that" it will not be attacked" by components within the coating. (US 258, Col. 3, lines 29 – 37). Chavannes expressly teaches cleaning of its carrier surface with a driven buffing brush. (US 258, Col. 6, lines 52 – 62).

Goldsworthy is directed to the continuous fabrication of polyurethane foam insulation. (US 106, Col. 1, lines 55 – 60). Goldsworthy applies polymer that has been metered and mixed together via a "standard" machine to three dimensional filaments disposed on the surface of a belt which has been coated with a wax or an equivalent release agent. (US 106, Col. 2, lines 25 - 28 and 44 – 45). After curing sufficiently, the foamed material is "cut" from the belt. (US 106, Col. 2, lines 39 – 41). After cutting the cured/dried material from the belt, the belt is "cleaned" and subsequently re-coated with a wax or release agent. (US 106, Col. 2, lines 43 – 47) Suitable cleaning methods include mechanical cleaning and solvent cleaning. (Col. 2, line 44).

Barth is directed to particular dryers that have been contaminated by volatilized medicinal residues. (US 761, Col. 1, lines 33 – 38). Barth is particularly directed to transdermal therapeutic system dryer systems that avoid "contamination from residues of previous charges" and prevent the escape of substances into the atmosphere. (US 761, Col. 1, lines 57 – 64). The dryers of Barth have cup-shaped, rounded wall elements enabling rapid disassembly for cleaning. (US 761, Col. 2, lines 31 – 49). A "self-supporting" sheet of material is guided through the dryer. (US 761, Col. 4, lines 35 – 40). Barth further teaches that solvents and medicinal residues escaping as the sheet of material is dried may be burned. (US 761, Col. 3, lines 49 – 51).

The only references that address cleaning of foraminious surfaces, clearly indicates the use of either brushes (Chavannes) or any of mechanical means, "heat" or solvents (Goldsworthy). Thus one skilled in the art would have considered mechanical and thermal cleaning as functional equivalents, based on the teachings of Goldsworthy, as indicated by the Examiner in the outstanding Office Action on Page 6, last full paragraph. Mechanical cleaning, by definition, is limited to the solid's surface. Consequently, it was altogether unpredictable to one skilled in the art that the recited thermal treatment would remove contaminating substances diffused into the carrier material, as recited in the claimed invention. Contrary to the apparent assertions within the outstanding Office Action on Page 7, last partial paragraph, the "residual material" removed by the cited references was clearly material remaining at the surface of the foraminious surfaces, as evidenced by Chavannes' use of brushes and Goldsworthy's use of mechanical means.

Furthermore, the Examiner's statement on Page 7, last partial paragraph that the generic "thermal treatment" of Goldsworthy (who does not disclose any reccommended temperatures or dwell times for such treatment) would be sufficient to remove residual material diffused into the carrier, because "all cast components will have a diffusion coefficient ...that will increase as a result of the elevated temperature" is a purely conclusory statement based on an entirely hindsight analysis. The further statement in the outstanding Office Action on Page 8, first partial paragraph, last sentence, that the teachings of the cited references "necessarily result in the removal of diffusion contamination," likewise constitutes a conclusory statement. Goldsworthy, the only reference to even generically note the thermal treatment of foraminious surfaces, provides absolutely no guidance as to suitable conditions. Hence the Office Action's statements as to the "necessary" removal of diffusion contaminants that none of the cited references even recognize as existing is purely conjecture.

In fact, the Office Action's inference that diffused contaminants would be even be present within Chavannes and Goldsworthy (based upon the foregoing statements within the outstanding Office Action) is likewise conjecture. Chavannes states that his foraminious surface has been specifically coated so that" it will not be attacked" by components within the coating. Goldsworthy similarly teaches the re-coating of its foraminious surface with a wax subsequent to foam removal. The remaining references do not teach or suggest contaminants diffusing into a carrier material. Suzuki, the primary reference, instead teaches its compositions may be cast onto a glass plate, for example. Consequently, the combination of references does not teaches or suggest the presence of diffused contaminants within a carrier material, much less the removal of such diffused contaminants by the recited thermal treatment.

The combined prior art, considered in view of common knowledge at the time of the invention, is required to at least suggest the claimed invention in its entirety. As indicated, above, this burden has clearly not been met. Accordingly, Applicants respectfully submit that Claims 3, 5, 6, 9 and 10 are patentable over Suzuki in view of Schmidt; McGinity; Chavannes (including Chavannes-2 and Ventouras); Goldsworthy and Barth.

B. Claims 1 and 7 are likewise patentable over Suzuki in view of Schmidt; McGinity; Chavannes; Goldsworthy; Barth; and further in view of Lerdkanchanaporn A and Lerdkanchanaporn B.

B1. Claims 1 and 7 are patentable over Suzuki in view of Schmidt; McGinity; Chavannes; Goldsworthy; Barth and further in view of Lerdkanchanaporn A and Lerdkanchanaporn B because, inter alia, their combination was improper.

As discussed in greater detail above, the combination of Suzuki, Schmidt, McGinity, Chavannes; Goldsworthy and Barth is improper because Chavannes (including applied but not-cited Chavannes-2 and Ventouras), Goldsworthy and Barth are in a different field of endeavour from Suzuki, Schmidt, McGinity, and the claimed invention, and none of references are pertinent to the particular problem with which the inventor is involved. Lerdkanchanaporn A and Lerdkanchanaporn B are likewise in a different field of endeavour from Suzuki, Schmidt, McGinity and the claimed invention, and are similarly not pertinent to the particular problem with which the inventor is involved.

As noted above, the present invention is directed to methods by which to remove active-ingredient-contaminants that have diffused into carrier materials used to produce consumable active-ingredient-containing films, so that the carrier materials may be used to form further consumable films. Lerdkanchanaporn A merely studies the effect of starch on the evaporation onset temperature of ibuprofen. Lerdkanchanaporn B merely profiles the evaporation behavior of ibuprofen between its melting point and boiling point. Consequently, Lerdkanchanaporn A and Lerdkanchanaporn B are clearly not within the inventor's field of endeavour.

Lerdkanchanaporn A and Lerdkanchanaporn B are further not directed to methods by which to remove contaminants that have diffused into a carrier material, but are instead directed to significantly different purposes, i.e. they solve altogether different problems. Consequently, neither Lerdkanchanaporn A or Lerdkanchanaporn B would have commended themselves to the inventor's attention in considering the problem of contaminants diffused within a carrier

material, much less a carrier material used to form consumable films. Lerdkanchanaporn A and Lerdkanchanaporn B are neither directed to the removal of contaminants that have diffused into carrier material or even to consumable films. Specifically, Lerdkanchanaporn A, studying the effect of starch on the evaporation onset temperature of ibuprofen, and Lerdkanchanaporn B, profiling the evaporation behavior of ibuprofen, simply do not have the same purpose and do not relate to the same problem as the claimed invention.

Accordingly, the combination of Lerdkanchanaporn A and Lerdkanchanaporn B with Suzuki, Schmidt, McGinity is likewise improper, and they should be entirely excluded from consideration in the non-obviousness analysis. None of the remaining references, even those directed to consumable films, teaches or suggests the removal of contaminants from carrier material.

B2. Claims 1 and 7 are patentable in further in view of Lerdkanchanaporn A and Lerdkanchanaporn B because, inter alia, the claimed invention solved an unrecognized problem.

The claimed invention is patentable because none of the cited references recognizes contaminants which have diffused into a carrier material as an issue, and most certainly not contaminants that have diffused into a carrier material used to form consumable films. Lerdkanchanaporn A and Lerdkanchanaporn B, both solely directed to the evaporative behavior or ibuprofen, do not cure the deficiency in the remainder of the cited references.

B3. Claims 1 and 7 are patentable in further view of Lerdkanchanaporn A and Lerdkanchanaporn B because, inter alia, the claimed invention provides more than predictable results.

The claimed invention is patentable because none of the cited references teaches or suggests that thermal treatment could remove contaminants which have diffused into a carrier material, thus the claimed invention provides more than predictable results. Lerdkanchanaporn A and Lerdkanchanaporn B do not cure the deficiency in the remainder of the cited references.

B4. Claims 1 and 7 are patentable in further view of Lerdkanchanaporn A and Lerdkanchanaporn B because, inter alia, the combination does not teach or suggest the claimed thermal treatment at approximately 80 °C.

Even if Suzuki, Schmidt, McGinity, Chavannes, Goldsworthy, Barth, Lerdkanchanaporn A and Lerdkanchanaporn B were combined (which Applicants did not do) the invention of Claims 1 and 7 would not have resulted. Specifically, the combination of Schmidt, McGinity, Chavannes, Goldsworthy, Barth, Lerdkanchanaporn A and Lerdkanchanaporn B does not teach the claimed thermal treatment at approximately 80 °C, much less such thermal treatment with a dwell time of 0.5 to 6 minutes.

Lerdkanchanaporn B teaches that ibuprofen melts at 80 °C and has a boiling point ranging from 212 to 251 °C. (Journal of Thermal Analysis, Abstract). Lerdkanchanaporn B provides a coefficient of evaporation for ibuprofen corresponding to temperatures ranging from 403 K (i.e. 130 °C) to 453 K (i.e. 180 °C) (Journal of Thermal Analysis , Conclusion). The cited portion of Lerdkanchanaporn A teaches that the melting point of ibuprofen is actually 75 – 77 °C, at which point evaporation begins, and further that the ibuprofen is "often" exhausted evaporatively before reaching its boiling point. (Thermochimica, Col. 1, paragraph 1).

Applicants respectfully submit that there would have been no motivation to have selected the recited thermal treatment at approximately 80 °C based upon the teachings of Lerdkanchanaporn A and Lerdkanchanaporn B. Particularly, there would have been no motivation to have selected the approximate melting temperature of ibuprofen as a suitable temperature to remove residual contaminants from a carrier material, as the evaporation rate for ibuprofen would have been expected to be minimal at that point. Although evaporation arguably does begin at the melting point of ibuprofen, the evaporation rate would be expected to increase significantly as the temperature approached the boiling point of ibuprofen, i.e. 212 to 251 °C. Thus in order to remove contaminant quickly, one would have been motivated to have chosen a higher thermal treatment temperature than the melting temperature of any particular active

ingredient. Furthermore, the claimed invention may be used with any of a number of active ingredients, and is in no way limited to ibuprofen.

Consequently, Claims 1 and 7 are patentable in light of the combination of Suzuki, Schmidt, McGinity, Chavannes, Goldsworthy, Barth in further view of Lerdkanchanaporn A and Lerdkanchanaporn B, as the foregoing combination does not teach or suggest the claimed thermal treatment at approximately 80 °C, and most certainly not such a thermal treatment with a dwell time of 0.5 to 6 minutes.

C. Claims 1 and 8 are similarly patentable over Suzuki in view of Schmidt; McGinity; Chavannes, Goldsworthy Lerdkanchanaporn A and Lerdkanchanaporn B, Dieudonne and Wimberger.

C1. Claims 1 and 8 are patentable over Suzuki in view of Schmidt; McGinity; Chavannes; Goldsworthy; Lerdkanchanaporn A, Lerdkanchanaporn B in further view of Dieudonne and Wimberger because, inter alia, their combination was improper.

As discussed in greater detail above, the combination of Suzuki, Schmidt, McGinity, Chavannes; Goldsworthy, Lerdkanchanaporn A and Lerdkanchanaporn B is improper because Chavannes (including applied but not-cited Chavannes-2 and Ventouras), Goldsworthy, Lerdkanchanaporn A and Lerdkanchanaporn B are in a different field of endeavour from Suzuki, Schmidt, McGinity, and the claimed invention, and none of references are pertinent to the particular problem with which the inventor is involved. Dieudonne and Wimberger are likewise in a different field of endeavour from Suzuki, Schmidt, McGinity and the claimed invention, and are similarly not pertinent to the particular problem with which the inventor is involved.

As noted above, the present invention is directed to methods by which to remove active-ingredient-contaminants that have diffused into carrier materials used to produce consumable active-ingredient-containing films, so that the carrier materials may be used to form further consumable films. Dieudonne is directed to continuous ovens for producing printed circuit

boards. Wimberger is directed to air floatation driers for graphic arts. Consequently, Dieudonne and Wimberger are clearly not within the inventor's field of endeavour.

Dieudonne and Wimberger are further not directed to methods by which to remove contaminants that have diffused into a carrier material, but are instead directed to significantly different purposes, i.e. they solve altogether different problems. Consequently, neither Dieudonne or Wimberger would have commended themselves to the inventor's attention in considering the problem of contaminants diffused within a carrier material, much less a carrier material used to form consumable films. Dieudonne and Wimberger are neither directed to the removal of contaminants that have diffused into carrier material or even to consumable films. Specifically, Dieudonne, providing a specific auxiliary drive band in ovens used to solder circuit boards to improve thermal conditions of the circuit boards, and Wimberger, using solvent-laden air as a heat source within a graphic arts dryer for greater efficiency, simply do not have the same purpose and do not relate to the same problem as the claimed invention.

Accordingly, the combination of Dieudonne and Wimberger with Suzuki, Schmidt, McGinity is likewise improper, and they should likewise be entirely excluded from consideration in the non-obviousness analysis. None of the remaining references, even those directed to consumable films, teaches or suggests the removal of contaminants from carrier material.

C2. Claims 1 and 8 are patentable in further in view of Dieudonne and Wimberger because, inter alia, the claimed invention solved an unrecognized problem.

The claimed invention is patentable because none of the cited references recognizes contaminants which have diffused into a carrier material as an issue, and most certainly not contaminants that have diffused into a carrier material used to form consumable films. Dieudonne and Wimberger, respectively directed to circuit board ovens and graphic arts dryers, do not cure the deficiency in the remainder of the cited references.

C3. Claims 1 and 8 are patentable in further view of Dieudonne and Wimberger because, inter alia, the claimed invention provides more than predictable results.

The claimed invention is patentable because none of the cited references teaches or suggests that thermal treatment could remove contaminants which have diffused into a carrier material, thus the claimed invention provides more than predictable results. Dieudonne and Wimberger do not cure the deficiency in the remainder of the cited references.

C4. Claims 1 and 8 are patentable in further view of Dieudonne and Wimberger because, inter alia, the combination does not teach or suggest the claimed thermal treatment at approximately 80 °C.

Even if Suzuki, Schmidt, McGinity, Chavannes, Goldsworthy, Lerdkanchanaporn A, Lerdkanchanaporn B, Dieudonne and Wimberger were combined (which Applicants did not do) the invention of Claims 1 and 8 would not have resulted. Specifically, the combination of Schmidt, McGinity, Chavannes, Goldsworthy, Lerdkanchanaporn A, Lerdkanchanaporn B, Diuedonne and Wimberger does not teach the claimed thermal treatment at approximately 80 °C, much less such a thermal treatment having a dwell time of approximately 0.5 to 6 minutes.

Diuedonne is directed to continuous ovens for soldering printed circuit boards fitted with electronic components that include a particular conveying device that carries the printed circuit board through the oven. (US 836, Col. 1, lines 21 – 66). The ovens of Dieudonne include electrical infrared heat radiators for the thermal treatment of the circuit boards and a conveying device having two synchronously driven, continuous drive bands, with an auxiliary drive band disposed therebetween. (US 836, Col. 1, lines 67 – 68 and Col. 2, lines 60 – 65). Dieudonne notes the use of "very high temperatures" within his ovens, as the "necessary soldering temperature … is at approximately between 180 °C to 185 °C. (US 836, Col. 1, lines 40 – 45).

Wimberger is solely directed to air floatation driers for graphic arts that use solvent-laden air as their sole or primary heat source in generating high drying temperatures. (US 220, Col. 1, lines 14 – 19 and Col. 2, lines 45 - 51). Wimberger's driers are intended to dry ink on paper using a raw gas burner. (US 220, Col. 6, lines 1 – 6 and 20 - 23). Wimberger expressly notes dryer temperatures ranging from 200 °F (93 °C) to 500 °F (i.e. 260 °C) as suitable. (US 220, Col. 6, lines 6 – 7).

Applicants respectfully submit that there similarly would have been no motivation to have selected the recited thermal treatment at approximately 80 °C based upon the teachings of Dieudonne and Wimberger. Particularly, there simply would have been no motivation to have selected such a moderate temperature in light of Dieudonne's teaching of 180 °C to 185 °C and Wimberger's teaching of temperatures ranging from 93 °C to 260 °C.

Consequently, Claims 1 and 8 are patentable in light of the combination of Suzuki, Schmidt, McGinity, Chavannes, Goldsworthy, Lerdkanchanaporn A, Lerdkanchanaporn B, Dieudonne and Wimberger, as the foregoing combination does not teach or suggest the claimed thermal treatment at approximately 80 °C, much less the recited moderate thermal treatment temperature at a dwell time of 0.5 to 6 minutes.

Consequently, Claims 1 and 8 are patentable in light of the combination of Suzuki, Schmidt, McGinity, Chavannes, Goldsworthy, Lerdkanchanaporn A, Lerdkanchanaporn B, Dieudonne and Wimberger, as the foregoing combination does not teach or suggest the claimed thermal treatment at approximately 80 °C, and most certainly not such a thermal treatment with a dwell time of 0.5 to 6 minutes.

VIII. CONCLUSION

For the reasons argued above, the reversal of the rejection of Claims 1, 3 and 5 through 10 under 35 USC § 103 is respectfully requested.

Respectfully submitted,

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Claire Wygand Ms. Claire Wygand

CLAIMS APPENDIX

1. A method for removing contaminating substances from a carrier material comprising

a) heating an active-ingredient- containing drug, food or cosmetic-containing coating to approximately 40 to 100 °C,

b) coating the heated active-ingredient- containing drug, food or cosmetic coating onto a neutralized carrier material via synchronized rollers, substances within said coating diffusing into and thereby contaminating said carrier material with drug, food or cosmetic contaminating substances,

c) drying the coated carrier material to form an active-ingredient-containing drug, food or cosmetic film,

d) peeling the dried active-ingredient- containing film off the contaminated carrier material and

e) subjecting the contaminated carrier material to a thermal treatment which comprises

i) passing said contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminating substances from the carrier material to form neutralized carrier material, and

ii) feeding the removed contaminating substances to a thermal after-burning using controlled air circulation, and

f) providing the neutralized carrier material to said coating step,

wherein said thermal treatment is performed at a temperature of approximately 80 °C and the period of time sufficient to remove essentially all of the undesired substances from the carrier material is approximately 0.5 to 6 minutes and said carrier material is supplied on a reel,

and said carrier material is paper, a polymer or a composite material composed of paper, polymer or a thin metal foil or polymer and a thin metal foil.

2. (Canceled)

3. A method according to claim 6, wherein said carrier material is paper, a polymer or a composite material composed of paper, polymer or a thin metal foil or polymer and a thin metal foil.

4. (Canceled)

5. A method for removing contaminating substances from a carrier material comprising

a) heating an active-ingredient- containing drug, food or cosmetic aqueous coating to approximately 40 to 100 °C,

b) coating the heated active-ingredient- containing drug, food or cosmetic coating onto carrier material via synchronized rollers, substances within said aqueous coating composition diffusing into and thereby contaminating said carrier material,

c) drying the coated carrier material to form an active-ingredient-containing drug, food or cosmetic film,

d) peeling the dried active-ingredient- containing film off the contaminated carrier material and

e) subjecting the drug, food or cosmetic contaminated carrier material to a thermal treatment comprising

i) passing said contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the drug, food or cosmetic contaminating substances from the carrier material and

ii) feeding the removed contaminating substances to a thermal after-burning using controlled air circulation.

6. A method for removing contaminating substances from a carrier material comprising

a) heating an active-ingredient- containing drug, food or cosmetic-containing coating to approximately 40 to 100 °C,

b) coating the heated active-ingredient-containing drug, food or cosmetic coating onto carrier material via synchronized rollers, active ingredients, adjuvants, flavors, or fragrances within said coating diffusing into and thereby contaminating said carrier material,

c) drying the coated carrier material to form a drug-containing film, confectionary-containing film, food -containing film or cosmetics-containing film,

d) peeling the dried film off the contaminated carrier material and

e) subjecting the contaminated carrier material to a thermal treatment comprising

i) passing said contaminated carrier material through a thermal treatment zone at a temperature and during a period of time sufficient to remove essentially all of the contaminating substances from the carrier material and

ii) feeding the removed contaminating substances to a thermal after-burning using controlled air circulation.

7. A method according to Claim 1, said method further comprising
optionally cooling the treated carrier, and
coating the treated and optionally cooled carrier,
wherein said thermal treatment is imparted in a drying tunnel.

8. A method according to Claim 1, wherein said thermal treatment consists of an infra red heat treatment.

9. A method according to Claim 5, said method further comprising taking the thermally treated carrier material up on a reel.

10. A method according to Claim 6, said method further comprising taking the thermally treated carrier material up on a reel.

EVIDENCE APPENDIX

No separate evidence has been submitted in the above-referenced application.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings and therefore no final decisions have been rendered in related proceedings.